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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,839	03/01/2001	John R. White	P 50836	6619

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,839	WHITE, JOHN R.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *May 24, 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4 and 6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4 and 6* is/are rejected.

7)☒ Claim(s) *2 and 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

1. Claims 1, 3, 4 and 6 are rejected under 35 U.S.C. 1 12, first paragraph, because the specification, while being enabling for N-[2-Hydroxy-4-cyanophenyl]-N'-[2-bromophenyl] urea or N-[2-Hydroxy-4-nitrophenyl]-N'-[2-bromophenyl] urea , does not reasonably provide enablement for all compounds which bind to the CXCR2 receptor or CXCR1 receptor and effectively inhibit T-cell mediated chemotaxis or block the binding of neutrophils to activated endothelial cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The following is responsive to applicant's amendment received May 24, 2004.

No claims are cancelled. No new claims are added. Claims 1-6 are currently pending.

The previous objection of claim 2 set forth in paragraph 2 of the office action mailed Nov. 19, 2003 is withdrawn in view of applicant's amendment and the remarks contained therein.

The previous objection to the specification (paragraph 3 of the office action mailed Nov. 19, 2003) is withdrawn in view of applicant's amendment and the remarks contained therein.

However, applicant's arguments traversing the previous rejection of claims 1, 3, 4 and 6 under 35 USC 112, first paragraph (paragraph 1 of the office action mailed Nov. 19, 2003) have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed Nov. 19, 2003 with the following additional comment.

Applicant asserts that the examiner misconstrues the invention and has failed to take into consideration the entirety of applicant's disclosure. Specifically, Applicant argues that the specification discloses more than a reasonable number of compounds that are capable of accomplishing the claimed invention. Specific reference is made to page 3, lines 12-19, where thousands of compounds varying in structure are known to be IL-8 receptor antagonists and are useful in the claimed the inventions.

Said arguments have been considered but are not found to be persuasive.

According to MPEP 2164.08, the Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation'." In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. > AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003);< In re Moore, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003).

In this case, the Examiner respectfully submits that the scope of enablement in the disclosure does not bear a "reasonable correlation" to the scope of the claims. The references cited at page 3, lines 12-19 of the specification fail to adequately enable the scope of the claimed methods. It is acknowledged that the Office does not require the presence of working examples to be present in the disclosure of the invention (MPEP 2164.02) However, in light of the state of the art, which recognizes the unpredictable nature of the pharmaceutical and chemical art, the Office would require appropriate disclosure to support the contention that the administration of any one of the claimed compounds, including those listed on page 3 of the specification, could actually inhibit the binding of human neutrophils to activated endothelial cells or inhibit T-cell mediated chemotaxis in a human. The present specification fails to enable one of ordinary skill in the art to practice the invention insofar as it reads on the use of any compound capable of binding the CXCR2 receptor. Given the breadth of what is presently claimed, what is presently disclosed, what is supported by adequate description in the specification and, further, given the breadth and variety of compounds (as evidenced by the list of compounds on page 3 of the specification), the skilled artisan would have no alternative course but undue experimentation in order to determine which of the thousands of compounds disclosed would be capable of performing the claimed methods.

Applicant's specification, on the other hand, is enabled for the use of N-[2-Hydroxy-4-cyanophenyl]-N'-[2-bromophenyl] urea or N-[2-Hydroxy-4-nitrophenyl]-N'-[2-bromophenyl] urea in the claimed methods. Data from working examples that relate to only two compounds does not reasonably correlate to the scope of the claims which may encompass thousands of compounds (at least), each of which vary in structure. The scope of enablement provided to one

of ordinary skill in the art by Applicant's disclosure is not commensurate with the scope of protection sought by Applicant's claims. Therefore, the examiner respectfully maintains that one of ordinary skill in the art would be burdened with undue experimentation to practice the full scope of the claimed method.

Therefore, the rejection is respectfully maintained.

Claims 2 and 5 remain objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1, 3, 4 and 6 stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
Jan. 9, 2006

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